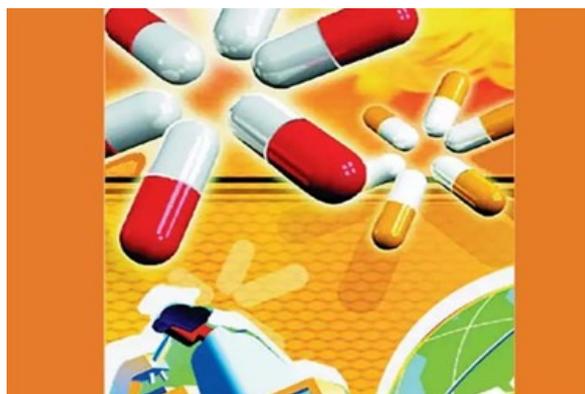




'Gilead's Key Drug Used In HIV-Related Infection Out Of Reach In Developing Countries'



Mumbai, India: Pharma major Gilead Sciences has failed to deliver on promises to make an important drug available to patients suffering from a life-threatening HIV-related infection in certain developing countries including India, the medical humanitarian organisation Médecins Sans Frontières (MSF) said.

Nearly one year ago, Gilead announced its 'access initiative' promising lower prices for liposomal amphotericin B in 116 developing countries, but to date, the drug largely remains inaccessible, a MSF statement adds. Although Gilead had announced a special price of \$16.25 per vial for liposomal amphotericin B (L-AmB) in September 2018 for developing countries, L-AmB continues to be priced out of

reach in many developing countries. For example, in India it is priced at \$45 per vial (nearly \$1,000 per full treatment course), while in South Africa as high as \$200 per vial (at least \$4,200 per full treatment course).

L AmB is highly effective when used in combination with other medicines to treat cryptococcal meningitis, which is the second biggest killer of people living with HIV, after tuberculosis. Cryptococcal meningitis is an infection of the brain, which if left untreated, results in an agonising death for people living with HIV. According to the WHO cryptococcal meningitis is a serious infection which is a major cause of morbidity and mortality in people living with HIV with advanced disease, accounting for an estimated 15% of all AIDS-related deaths globally. An estimated 223,100 cases of cryptococcal meningitis result in 181,000 deaths each year among people living with HIV.

Over a year ago, the drug was recommended by World Health Organization (WHO) as the preferred treatment over a sub-optimal, more toxic treatment (AmB deoxycholate), as the safety benefits and fewer side effects associated with L-AmB could improve treatment outcomes and management in low-resource settings where most cases of cryptococcal meningitis occur. WHO, however, recognised that high prices and a lack of registration of L-AmB created major barriers to people accessing this drug in developing countries.

"We are outraged that Gilead's announcement to provide this lifesaving drug at a supposed 'no profit' price and expedite its registration appears to have been nothing more than a public relations stunt," said Jessica Burry, MSF Access Campaign pharmacist. "The corporation has failed to make good on their promise to do more to help ensure the survival of people living with HIV affected by this deadly disease – it's deplorable that they keep dragging their feet at the expense of people's lives. Gilead must urgently honour their commitment to making L-AmB available for everyone who needs it, and quickly register the drug in high HIV-burden countries."

Gilead has a monopoly on L-AmB, though no longer under patent, the corporation has refused to license its technology and manufacturing methods to potential generic manufacturers, thereby delaying the availability of less expensive products. (Source: Health World)

Colluding Drug Firms ‘ Cost the NHS Millions of Pounds’



Four Pharmaceutical firms have been accused of illegally colluding to restrict the supply of an anti-nausea tablet, driving the price paid for it by the NHS up by 700%

The competition and Markets Authority (CMA) Said the cost of prochlorperazine rose from to £6.49 per pack to £51.68, after suppliers agreed not to compete.

The drug is often prescribed to cancer patients undergoing chemotherapy.

One of the firms named, Alliance Pharma, denied the allegations. In a statement of objections, the CMA says that between 2013 and 2018, the annual cost of 3mg dissolvable prochlorperazine tablets increased from approximately £2.7m to £7.5m, even though the NHS dispensed fewer packs during that period.

It claimed that sharp increase was the result of four companies - Alliance Pharma, Focus, Lexon and Medreich - agreeing not to compete against each other for the supply of the prescription-only pills.

Alliance supplied prochlorperazine exclusively to Focus, which the CMA says then paid Lexon a share of its profits from the sales.

Lexon, the competition regulator alleges, then shared these payments with Medreich. Patients are often prescribed prochlorperazine to help with dizziness

The CMA alleges that, before entering into this arrangement, Lexon and Medreich had been planning to launch their own jointly-developed prochlorperazine.

In s statement, Alliance said it had" no involvement in the pricing or distribution of prochlorperazine since 2013, when it was out-licensed by the company to Focus Pharmaceuticals Limited on an Exclusive basis as is normal market practice".

The firm added:" Alliance has not had control of or influence on, and nor has it benefited from, any price increases".

The BBC has contacted Focus, Lexon Medreich for Comment.

The CMA's Ann Pope said:" Agreement where a company a rival not to enter the market can lead to higher prices and deprive the NHS of savings that often result from competition between drug suppliers.

"The NHS should not be denied the opportunity of benefitting from an increased choice of supplier, or lower prices, for important medicine."

The companies concerned will now have the opportunity to respond to the CMA's Provisional finding.

If it eventually determines that competition law has been broken, the CMA can impose a financial penalty of up to 10% of each company's worldwide turnover. (Source: BBC)

Two Thirds of AIDS Treatment Drugs Supplied Globally by India

UNITED NATIONS: Taking a lead in the global fight against AIDS, India is supplying the world with two-thirds of the drugs to treat those infected with HIV, according to Indian diplomat Paulomi Tripathi.

"These affordable generic medicines have helped scale up access to treatment across developing countries," Tripathi, a First Secretary in India's UN mission, told the General Assembly on Monday. India is contributing in the international fight against AIDS: almost two-thirds of the antiretroviral drugs used globally are supplied by the Indian pharmaceutical industry," she said during a discussion on the Implementation of the Declaration of Commitment on HIV/AIDS and the political declarations on HIV/AIDS adopted by the General Assembly in 2001.

Tripathi emphasised the importance of continued political commitment to ensure that competing financing demands and changing priorities did not affect efforts to provide adequate resources to fighting HIV/ AIDS.

"Ensuring uninterrupted access of affordable antiretroviral drugs and quality care, as well as adherence to treatment through support services, is necessary to combat drug resistance," she said.

Domestically, "the focus is on reduction in new infection, elimination of stigma and discrimination by 2020," she added.

New infections have declined in India by more than 80 per cent from peak of epidemic in 1995 and deaths from the disease have come down by 71 per cent since its peak in 2005, she said.

Tripathi ascribed the progress to the involvement of communities, civil society and people living with HIV in policy and delivery of services and through intensified information, education and communication drives.

India, which is described as the pharmacy to the world has a special licence the UN-backed Medicines Patent Pool to manufacture anti-AIDS medicine TenofovirAlafenamide (TAF) for 112 developing countries.

According to a 2017 study by Harvard Business School, low-cost generic antiretroviral drugs from India "have been integral to the rapid scale-up of HIV treatment in Sub-Saharan Africa and other developing countries".

"A common first-line regimen of treatment decreased from \$414 per person per year to \$74 per person per year for Indian generics," it said.

Secretary-General Antonio Guterres said in his report that when the General Assembly held its first session on the AIDS epidemic in 2001 a "world without AIDS was almost unimaginable". However, "the global determination to defeat one of history's greatest health crises has produced remarkable progress", he said.

The number of HIV-infected people around the world, the number receiving treatment has increased 5.5 times over the last decade, and behaviour change communications and condom distribution programmes have successfully reduced the spread of AIDS and many countries have eliminated mother-to-child transmission of HIV, Guterres said. (Source:IndianPharma.in)

As Price of Insulin Soars, Americans Caravan to Canada for Lifesaving

As their minivan rolled north, they felt their nerves kick in — but they kept on driving. At the wheel: Lija Greenseid, a rule-abiding Minnesota mom steering her Mazda5 on a cross-border drug run.

Her daughter, who is 13, has Type 1 diabetes and needs insulin. In the United States, it can cost hundreds of dollars per vial. In Canada, you can buy it without a prescription for a tenth of that price.

So, Greenseid led a small caravan last month to the town of Fort Frances, Ontario, where she and five other Americans paid about \$1,200 for drugs that would have cost them \$12,000 in the United States. “It felt like we were robbing the pharmacy,” said Quinn Nystrom, a Type 1 diabetic who joined the caravan that day. “It had been years since I had 10 vials in my hands.”

They’re planning another run to Canada this month to stock up on insulin — and to call attention to their cause. This time, they’ll be taking the scenic route, driving from Minnesota through Wisconsin, Illinois, and Michigan en route to London, Ontario, where Frederick Banting began the work that led to the discovery of insulin nearly a century ago.

Like millions of Americans, Greenseid and Nystrom are stressed and outraged by the rising costs of prescription drugs in the United States — a problem Republicans and Democrats alike have promised to fix.

Insulin is a big part of the challenge. More than 30 million Americans have diabetes, according to the American Diabetes Association. About 7.5 million, including 1.5 million with Type 1 diabetes, rely on insulin.

Between 2012 and 2016, the cost of insulin for treating Type 1 diabetes nearly doubled, according to the nonprofit Health Care Cost Institute. Some pharmaceutical companies, under pressure from U.S. lawmakers, have tried to reduce the cost for some patients. But many who rely on insulin still struggle. Large numbers resort to rationing — a dangerous and sometimes deadly practice.

Some diabetics and their families are taking matters into their own hands. They meet in coffee shops and strip mall parking lots to exchange emergency supplies. An unknown number travel outside the country to buy the lifesaving drug for less.

None of this is recommended by U.S. officials, and some of it might be illegal under Food and Drug Administration guidelines. But the organizers of the caravan — their word, a nod to the migrants traveling in groups through Mexico to the U.S. border — are speaking out about their trip because they want Americans to see how drug prices push ordinary people to extremes.

“When you have a bad health-care system, it makes good people feel like outlaws,” Greenseid said. “It’s demeaning. It’s demoralizing. It’s unjust.”

The caravaners aren’t the only ones looking north. Republicans and Democrats have produced federal and state proposals to import drugs from Canada. (Source: The Washington Post)

UK Tie-Up Helps Improve Childhood Cancer Survival Rate



A collaboration between a British university and Indian institutions is helping improve the survival rates associated with childhood cancer in India.

The collaboration between the University of Manchester and the Tata Medical Centre in Kolkata is helping to improve cure rates in children with Acute Lymphoblastic Leukaemia (ALL) in India by 10-15 percent. The knowledge transfer from Manchester is also raising

standards of cancer care at Paediatric Cancer Centres in Delhi, Mumbai, Chennai and Chandigarh, the university said on International Cancer Survivors Day on Sunday.

Professor Vaskar Saha, a paediatrician from the University of Manchester, has helped cure children diagnosed with ALL by 15 percent during the five years he has led the Indian Childhood Collaborative Leukaemia Group (ICICLE) clinical project, in partnership with Tata Medical Centre in Kolkata. “In the UK, 450 children are diagnosed annually with ALL, of which 400 will survive. In India, 9,000 of the 15,000 children diagnosed annually will survive.”

“Not so long ago, four in ten Indian children would die because of poor treatment and relapse. The former was mainly due to the absence of standardisation in testing and treatment. If we can improve outcomes in India by 10 percent then an additional 1,500 children a year grow up to lead normal lives,” he said. Saha’s research has increased survival rates in Kolkata from 65 percent in 2014 to 80 percent in 2019, the university said

“It means that around 80 percent of children with the most common childhood cancer are now likely to survive following treatment at major centres across India, thanks to his revolutionary approach,” it said in a statement. Originally from West Bengal, Saha previously led research which helped increase survival rates among children with the condition by 10 Percent in the UK.

Saha is a professor of Paediatric Oncology at The University of Manchester and Senior Paediatric Consultant and Director of Translational Cancer Research at the Tata Medical Centre, Kolkata.

“With the help of colleagues in the NHS [the UK’s National Health Service] and across the world, we’ve successfully integrated modern diagnostics and monitoring into routine cancer care. This not only saves lives, it also saves money as children who don’t require intensive treatment are identified early and we are using IT tools to monitor and manage patients so they can return home early.”

Mammen Chandy, Director, Tata Medical Centre, Kolkata, said the institution was researching appropriate therapy through the ICICLE project, with the aim of collaborating with international specialists who can bring their skills and laboratories to India. With the ICICLE project, clinicians are able to share their knowledge in order to work towards standardised systems. (Source: News Experts)

Robotic Surgery Set for Huge Global Growth



Robotic surgery is set for dramatic global growth due to an increasing incidence of chronic diseases and the success of the minimally invasive technology in treating these, according to a new report.

In 2013 The Urology Hospital, Pretoria, became the first institution in South Africa to acquire a robotic surgical system and has to date performed about 1 800 robotic procedures, by far the majority of the country's total number — mostly prostatectomies (removal of cancerous prostate glands).

Other robotically assisted operations at the hospital include partial and full nephrectomies (removal of cancerous kidneys) and cystectomies (removal of the bladder) with urinary reconstruction. The technology is set to be applied to gynaecological, pelvic floor, colo-rectal and hernia procedures in the future.

The robotics report by Global Market Insights, notes that increased suffering from chronic disease, coupled with growing patient preference for minimally invasive procedures to prevent post-operative trauma and complications, is driving demand for robotic surgery. A separate study says that by next year, 80% of radical prostatectomies in the US will be performed robotically. A scientific review last year showed that robotic surgery provides better functional results than conventional procedures in the removal of cancerous prostate glands.

Urologist, Dr Hugo van der Merwe, said research shows that just over 23% of all South African men will be diagnosed with prostate cancer in their lifetime, adding: "robotic surgery is dramatically helping improve the treatment of prostate cancer by reducing the side effects and lowering levels of incontinence and impotence significantly compared to open surgery."

The Urology Hospital, Pretoria, is the only specialised hospital of its kind in the country, comprising 24 urologists, 11 of whom are trained in robotic surgery — the highest concentration of robotic surgeons in the country. The Hospital also houses the only robotic training facility in the country with three qualified robotic proctors available to train future robotic surgeons. Source: Spice4Life.com.za)

Drug Maker Sute To Block Requirement for Listing Prices In TV Ads.

Three of the nation's major drug manufacturers sued the Trump administration to block a rule that would force them to put the price of their drugs in television advertisements beginning this summer.

The lawsuit, filed in federal court in Washington, D.C., by Merck, Eli Lilly and Amgen, as well as a trade group for advertisers, argues that the rule is illegal because it violates the companies' First Amendment rights. It also claims that the ad disclosures, which require drug manufacturers to include the list price of any drug that costs more than \$35 a month, could mislead consumers because insurers often cover the bulk of a drug's cost.

"We believe the new requirements may cause patients to decide not to seek treatment because of their perception that they cannot afford their medications, when in fact many patients do not pay anything near list price," Merck, whose top-selling product is the pricey cancer drug Keytruda, said in a statement. Lilly, which is one of three manufacturers of insulin under scrutiny for rising list prices — said the federal government had overstepped its authority. "The impetus for the lawsuit is drug prices in TV ads, but the crux of it is H.H.S. not having the authority to mandate this action," the company said in a statement, referring to the Department of Health and Human Services.

The trade group, the Association of National Advertisers, was also listed as a plaintiff in the suit. Dan Jaffe, an executive vice president for the group, said they joined the suit because the rule "would substantially undermine First Amendment protections for advertisers and would certainly create precedent that would go far beyond the prescription drug area."

Alex M. Azar II, the secretary of health and human services, announced the new rule in May, contending that forcing pharmaceutical companies to disclose their prices could push companies to lower them. He was a top executive at Lilly before joining the Trump administration in January 2018. "If the drug companies are embarrassed by their prices or afraid that the prices will scare patients away, they should lower them," Caitlin Oakley, a spokeswoman for the health and human services department, said in a statement. "President Trump and Secretary Azar are committed to providing patients the information they need to make their own informed health care decisions."

Many drug companies, anticipating the rule, had set up their own websites with information that included list prices, as well as typical out-of-pocket costs and sources of financial assistance. Johnson & Johnson said this year that its ads would begin disclosing the list price, starting with those for the anti-stroke drug Xarelto that carries a \$448 monthly list price, along with information about the typical consumer co-payment. (Source: The New York Times)

Insulin Pumps are Vulnerable to Hacking, FDA Warns Amid Recall

The Food and Drug Administration is warning insulin pump users about potential cybersecurity and hacking risks involved with some devices.

According to an announcement released, the MiniMed 508 and the MiniMed Paradigm insulin pumps from Medtronic are vulnerable to possible hacking and are being recalled. If a patient is using one of the pumps, they could be at risk of "an unauthorized person with special technical skills and equipment" connecting to the device and changing how much insulin is delivered, according to a letter sent to patients and health-care providers and posted on Medtronic's website.

"While we are not aware of patients who may have been harmed by this particular cybersecurity vulnerability, the risk of patient harm if such a vulnerability were left unaddressed is significant," Suzanne Schwartz, an FDA official specializing in cybersecurity for medical devices, said in a statement. Internet of things According to the FDA, an individual "could potentially connect wirelessly to a nearby MiniMed insulin pump and change the pump's settings." This could spur dire health concerns. Hypoglycemia could occur if too much insulin is delivered. It could also cause too little insulin to be delivered, and a diabetes patient could suffer from hyperglycemia and diabetic ketoacidosis. (Source: Washington Post)